

Appl. No. 10/064,710  
Atty. Docket No. 9008  
Amdt. dated March 18, 2004  
Reply to Office Action of December 18, 2004  
Customer No. 27752

### REMARKS

Claims 1-18 are pending in the present application. No additional claims fee is believed to be due.

Claim 14 is cancelled without prejudice.

Claim 16 has been amended to correct a typographical mistake regarding the term "effective" instead of "effect of". Support for this amendment is found, *inter alia*, at page 2, paragraph 9 of the specification. Claims 17 and 18 have been amended to remove the repeated words "for preventing". Claim 12 has been amended to remove the repeated words "calcium oxide".

Claim 10 has been amended to remove the language "for preventing a pregnancy or preventing a sexually transmitted disease". Support for the amendment could be found, *inter alia*, in the specification at paragraph 46.

Claim 11 has been amended to add an element. Support for this amendment could be found, *inter alia*, in the specification at paragraph 30.

Claim 8 has been amended to add words "anti-sexually transmitted disease". Support for the amendment could be found, *inter alia*, in the specification at paragraphs 44 and 45.

Claim 13 has been amended to remove words "a safe and effective amount and a". Support for the amendment could be found, *inter alia*, in the specification at paragraph 46.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

### Rejection Under 35 USC 112, First Paragraph

The Office Action states "Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for diminishing the risk of pregnancy and diminishing the risk of certain disclosed STDs with respect to disclosed known agents which are used to reduce the risk of pregnancy and STDs and condoms and diaphragms and in the appropriated administrative site, does not reasonably provide enablement for the use of activated carbon (AC) for the prevention of pregnancy or STDs, including reducing the risk thereof or all forms of administration or barrier agents in general. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims." Applicants respectfully disagree.

Applicants believe that the Office Action is using the factors discussed in *In re Wands* to determine whether the specification is enabled and whether undue experimentation is required to practice the invention. Applicants reproduce the relevant section from MPEP below:

#### **2164.01(a) Undue Experimentation Factors**

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement).

Applicants provide response for each of the factors considered by the Office Action:

##### *The nature of the invention:*

The invention is directed to compositions, kits and methods of preventing pregnancy or STDs by administering activated carbon. In some of the embodiments the invention employs other active agents along with activated carbon.

##### *The state of the prior art and the predictability or lack thereof in the art:*

The Office Action states "The prior art of record does not appear to show the effectiveness of activated carbon for prevention of pregnancy or STDs. Also, Banba, cited below,

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discloses a composition containing activated carbon which requires antibiotics to inhibit bacterial growth and which maintains the viability of sperm. As such, predictability in the art appears to be low." Applicants respectfully disagree.

Applicants wish to draw attention to many uses of activated carbon that are described succinctly in the US Patent 5,541,444 at col. 1, lines 17-31:

Activated carbon is characterized by a high specific surface area (e.g., 300 to 2500 m<sup>2</sup>/g) and is known for its high adsorptive capability. Activated carbon enjoys widespread use in the removal of impurities from fluid (i.e., liquid or gas) streams. For example, impurities in foods (e.g., fruit juices, alcoholic beverages) or medicinals (e.g., insulin, vitamins) can be successfully filtered using activated carbon. Likewise, activated carbon is useful in the removal of gaseous species present in low concentrations in air or gas streams (e.g., in gas separation processes, process for removal of organic vapors, or in cigarette filters). Activated carbon has particular utility in adsorbing and purifying fluid emissions from internal combustion engines.

US Patent 5,407,442 further describes carbon-containing odor controlling compositions. Also, water filters employing activated carbon have been used to remove particulate and soluble impurities from water since 1930s. Therefore, there is a high degree of predictability in the art with respect to both preparation and use of activated carbon. The art, on the other hand, does not teach or suggest the use of activated carbon for prevention of pregnancy or STDs, because it is the discovery by Applicants that activated carbon binds bacteria and sperm with high affinity and when used as described in the specification results in prevention of pregnancy or STDs (emphasis added).

US Patent 4,356,259 to Banba (hereinafter "Banba") discloses a method of preserving sperm of domestic animals. Banba uses a dialytic tube to store the sperm and places the tube containing sperm in a vessel that is filled with Ringer's solution containing an absorbent selected from the group consisting of albumin and activated carbon. In Banba, the sperm is never in physical contact with activated carbon. In fact, the activated carbon primarily functions to absorb the excretions that are generated by sperm when stored at low temperature for an extended period, providing the sperm with relatively purer Ringer's solution, thereby increasing the survival rate of sperm. Banba uses antibiotics to inhibit bacterial growth that may occur as the vessel is not sterile. The antibiotics used by Banba do not affect or enhance viability of sperm. In fact, the use of activated carbon by Banba to increase sperm viability actually points away from using activated carbon for preventing pregnancy or STDs (as discussed in detail below while responding to 35 U.S.C. 102(b), and 103 rejections in view of Banba).

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*The amount of direction or guidance present and the presence or absence of working examples:*

The Office Action states "Other than a general statement that AC is known to bind to pathogens, the only pathogens which are disclosed to bind to AC is *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. With respect to pregnancy, the Specification indicates that sperm has a strong affinity for AC. The Examples set forth in the Specification appear to be only prophetic in nature as opposed to actual data as no actual results appear to be given. As such, the only information provided is that pathogens and sperm bind to AC, however, no data is provided as to whether this has any effect on pregnancy or STDs." Applicants respectfully disagree.

Applicants assert that the specification provides sufficient written description and enabling disclosure for one skilled in the art to make and use the invention. It is known in the art that AC binds to many different bacteria, yeast, toxins, dyes, antibiotics, and other chemical substances. Paragraphs 25 through 29 provide a detailed description of ability of AC to bind bacteria that cause STDs and sperm. Applicants also provide probable mechanisms of action, without being bound by the theory, as to why AC may be successful at binding to bacteria that cause STDs or sperm. Further, in the Examples 1 at paragraph 62 and 63 Applicants demonstrate that clinical isolates of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* that cause STDs indeed bind to AC. In Example 2 Applicants show that human sperm also binds to AC with high affinity. Example 3 further demonstrates using two different protocols that AC when used in artificially inseminated New Zealand White Rabbits prevents pregnancy. *C. trachomatis* and *N. gonorrhoeae* represent two of the more common bacteria associated with STDs. Applicants have used them as representative STD-causing bacteria to show that the invention as described is enabled. One skilled in the art can readily conclude that other STD-causing organisms may also bind activated carbon. Thus, Applicants believe that there is no undue experimentation required. Further, MPEP § 2164.02 states,

#### WORKING EXAMPLES AND A CLAIMED GENUS

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation (emphasis added).

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As to the Office Action's contention that prophetic examples rather than actual data is provided, MPEP 2164.02 states,

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Applicants assert that the Examples provided are actual experiments that Applicants performed and are not prophetic in nature. Applicants have provided an enabling disclosure in the specification. The Example section is used to emphasize that Applicants were in possession of the invention as of the filing date of the application, and to provide guidance as to how to make and use the invention.

*The breadth of the claims and the quantity of experimentation needed:*

The Office Action states, "The claims broadly claim prevention of pregnancy and sexually transmitted disease by administration to a subject in need thereof. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to determine which pathogens bind to AC and whether is effective in preventing STDs and to determine whether binding of sperm to AC is effective in preventing pregnancy, and determining which is appropriate method of administration, or what other agents would serve as barriers". Applicants respectfully disagree.

Applicants have provided an enabling disclosure that teaches one skilled in the art to make and use the present invention. Applicants believe that no undue experimentation is needed to practice the invention. Applicants, in Examples 1-3 provide means for determining that AC

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binds to different bacteria that may cause STDs and sperm that may lead to pregnancy. Examples 4-8 then proceed to provide compositions that contain AC and other active ingredients, like Nonoxynol-9, triclosan, or chlorhexidene that are either surfactants, anti-metabolite agents, competitive binding inhibitors, or mixtures thereof. In the specification, at paragraphs 37 through 58, Applicants provide means and methods to make and use AC-containing compositions with other actives to achieve the goals of preventing pregnancy or STDs.

It is evident from the literature that many types of bacteria would bind AC. AC may or may not kill the bound bacteria. However, the binding of STD causing bacteria to the activated carbon inhibits them from colonizing the vaginal wall and thereby preventing STDs. The sperm on the other hand is a fragile biological material that may or may not survive once it is bound to AC. However, the sperm that is bound to the activated carbon is no longer able to move toward the oocyte, thereby achieving the inhibition of pregnancy. An animal body constantly secretes mucous into its body cavities, for example vagina; and periodic removal of these secretions (by voluntary or involuntary means) gets rid of accumulated microbes and/or sperm or other particulate matters. These actions assure that activated carbon-containing composition, and along with the bacteria or sperm that are bound to it are also removed from the body. Further, in some of the embodiments of the invention, removal of the AC-containing composition from its site of administration will result in removal of those bacteria or sperm. Once, the bacteria or sperm are removed with the AC-containing composition, there is a greatly diminished chance of the subject contracting STD or becoming pregnant. In some of the embodiments, Applicants have included other actives such as surfactants, anti-metabolite agents, competitive binding inhibitor agents or mixtures thereof, in order to provide other desirable benefits to the AC-containing composition. Therefore, Applicants believe that there is no undue experimentation needed in order to practice the invention.

Applicants submit that the specification discloses various routes of administration of activated carbon containing compositions to a subject. For example, paragraph 38 provides, "The ACs, compositions, or kits that comprise the present invention may be administered topically to a mucosal surface of a mammalian subject, preferably human subject, more preferably a female subject, in a body cavity where sexual contact may occur, that includes the vagina, rectum and mouth, in the prevention of a pregnancy or STD. The present invention is typically formulated for the particular mode of administration, i.e., vaginally, rectally, or orally."

Applicants teach in the specification how to make AC-containing compositions, either alone or in combination with other active ingredients. Applicants further provide when these compositions should be administered to work effectively in preventing pregnancy or STDs.

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Applicants also provide different preparations like, pessaries, tampons, suppositories, creams, gels, pastes, jelly, foams, sprays, aqueous or oily suspensions, solutions or emulsions, or films containing AC and optionally other ingredients. Thus, Applicants believe that the scope of the claims is commensurate with the disclosure and request that Examiner remove the rejections based on 35 U.S.C. 112, first paragraph.

Rejection Under 35 USC 112, Second Paragraph

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action further states "Claim 10 is indefinite as it is uncertain which of the listed ingredients are for preventing pregnancy or for preventing STDs and the specification does not appear to indicate which ingredients are for preventing pregnancy and which are for preventing STDs".

Claim 4 is directed to a composition that uses (a) a safe and effective amount of an activated carbon, as defined in the specification; and uses (b) a safe and effective amount of a spermicidal agent, an anti-STD agent, or mixtures thereof. Claim 10, which is dependent on claim 4, further comprises of other active ingredient that are non-AC, non-spermicidal agent, non-anti STD agent, or non-barrier agent that may be included for other purposes (Specification, paragraph 46). Applicants have amended the claim 10 and believe the rejection is overcome and request removal of the rejection.

The Office Action states, "Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the claims indicated a safe and effective amount of activated carbon but do not indicate what is the effect of the activated carbon." Applicants respectfully disagree.

The invention is directed to compositions, kits, and methods of preventing pregnancy or STDs by administering activated carbon. In the specification at paragraph 38-39, Applicants provide definitions for "a safe and effective amount" as well as "a unit dosage form" of an AC composition:

As used herein, a "safe and effective amount" of an AC, composition, or kit of the present invention is an amount that is effective to prevent a pregnancy or STD in a mammalian subject.

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preferably a human subject, more preferably a female human subject, without undue adverse effects (such as toxicity, irritation, or allergic response), commensurate with a reasonable benefit/risk ratio when used in the manner of the present invention. The specific "safe and effective amount" will, obviously, vary with such factors including, but not limited to, time between administration and sexual contact, multiplicity of sexual contacts, multiplicity of sexual partners, body cavity, risk of exposure to pathogens, the physical condition and reproductive age of the subject, the specific dose form to be used, the carrier employed, and the dosage regimen.

As previously described, one aspect of the invention provides for kits that comprise an AC and an anti-STD agent, spermicidal agent, or mixture thereof, in a unit dose form. As used herein, a "unit dosage form" is an amount of AC or agent that is suitable for administration to a mammalian subject, preferably a human subject, more preferably a human female subject, according to good medical practice. The unit dose forms preferably contain from about 1 milligram (mg) to about 1000 mg of the AC or agent. In one embodiment, the unit dose forms contain from about 3 mg to about 250 mg of AC or agent. If the AC and the spermicidal agent and/or anti-STD agent are combined in a single unit dose form, the unit dose form preferably contains from about 1 mg to about 1,500 mg of the AC and the agent(s) combined.

Further, throughout the specification, and particularly, at paragraphs 25-26, and paragraphs 28-29, Applicants describe that the AC of the invention has strong affinity for sperm and bacteria that cause sexually transmitted diseases, respectively. The effect of activated carbon is that both the sperm and the bacteria that cause STDs bind strongly to activated carbon. It is this property of AC that imparts it the ability to prevent pregnancy or contracting STDs after sexual contact. All the method or kit claims describe "a method of preventing a pregnancy" or "a method of preventing sexually transmitted diseases". Claims 1, 2, and 4, all use the term "A safe and effective amount". Claims 3, and 5-10 are dependent claims and therefore incorporate the same limitation. Claim 11 has been amended to include the term "a safe and effective amount", and therefore overcomes the rejection under 35 U.S.C. 112, second paragraph. Therefore, Applicants believe that there are no essential elements omitted from the claims, and request the rejection be withdrawn.

Rejection Under 35 USC 102(b) Over U.S. Patent 4,356,259 to Banba

Claims 5, 10, and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over Banba (US Pat. 4,356,259). The Office Action states, "Banba expressly discloses a container containing activated carbon, sodium



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bicarbonate, glucose, streptomycin and sulpenicillin, within the scope of applicant's claims (Example 1). Applicants respectfully disagree.

For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. ... These elements must be arranged as in the claim under review, ... but this is not an 'ipsissimis verbis' test. *In re Bond*, 910 F.2d 831, 15, USPQ2d 1566, 1567 (Fed. Cir. 1990). Applicants assert that Banba does not teach every element of the presently claimed invention.

The claim 1 of Banba is presented here for comparison.

Claim 1 A method of preserving sperm of domesticated animals comprising the steps of:

- (i) encapsulating a quantity of sperm in a dialytic tube;
- (ii) placing said dialytic tube in a vessel filled with Ringer's solution containing an absorbent selected from the group consisting of  
albumin and  
activated carbon

whereby a protective buffer layer of said solution surrounds said dialytic tube, and

- (iii) maintaining said dialytic tube and said vessel at a temperature of about 15° C.

As is apparent, Banba teaches a method of preserving a sperm sample from an animal by storing it at low temperature in a dialytic tube that allows free movement of small molecules that may include metabolic waste from sperm. These excretory products are then absorbed by either albumin or activated carbon thereby maintaining higher viability of sperm sample. In Banba's invention the sperm is never in direct contact with activated carbon. Banba states "An antibiotic substance such as streptomycin or sulpenicillin may be added to the sperm which is to be preserved so that the spermatozoa are prevented from being killed by the propagation of bacteria (Banba Specification, Col. 2, lines 55-58).

On the other hand, objected claims 5, 10, and 17, all claim either compositions or a kit containing compositions that possess a safe and effective amount of an activated carbon; and a safe and effective amount of a spermicidal agent, an anti-STD agent, or mixtures thereof. Claim

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10 further comprises of a yet another active ingredient. Applicant's invention is to prevent pregnancy or STDs in a female subject by providing a safe and effective amount of activated carbon to the subject. This is achieved by placing a composition containing activated carbon either before, during, or after sexual activity for a certain period. This allows the sperm and/or bacteria to bind directly to the activated carbon and either prevents sperm from fertilizing the egg, or prevents bacteria that cause STDs from colonizing the vaginal wall. The presence of a spermicidal agent or an anti-STD agent further assures prevention of pregnancy or STD, respectively. An animal body constantly secretes mucous into its body cavities, for example vagina; and periodic removal of these secretions (by voluntary or involuntary means) gets rid of accumulated microbes and/or sperm or other particulate matters. These actions assure that activated carbon-containing composition, and along with the bacteria or sperm that are bound to it are also removed from the body. Alternately, removal of the activated carbon-containing composition effectively removes the sperm and/or bacteria, thus preventing pregnancy or preventing STDs. In fact, Banba's use of

(i) activated carbon to increase the viability of sperm,

(ii) use of antibiotics to prevent bacteria,

and, Applicants use of

i. a spermicidal agent or an anti-STD agent,

ii. and specific routes of administration;

all teach away from using activated carbon for preventing pregnancy or preventing STDs.

Therefore, Applicants believe that Banba does not teach each and every element of the Applicant's invention, and request the rejection be removed.

Claims 5, 10, and 17 have been rejected under 35 USC 103(a) as being unpatentable over Banba. Applicants respectfully traverse this rejection. Banba does not establish a *prima facie* case of obviousness because it does not teach or suggest all of Applicants' claim limitations.

MPEP § 2143 states:

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants believe that the Office has not established a *prima facie* case of obviousness as required. First, as Applicants have already shown, Banba uses activated carbon to preserve sperm in a liquid environment, not to prevent pregnancy or kill sperm as the present invention claims. There is no suggestion or motivation in Banba to use activated carbon to prevent pregnancy or prevent STDs. Second, there is no expectation of success for using activated carbon upon reading of Banba. Banba never contemplates use of activated carbon to either prevent pregnancy or prevent STDs. In fact, as Applicants have already pointed out earlier, the teachings of Banba actually points one away from using activated carbon to prevent pregnancy or prevent STDs. And lastly, Banba does not teach nor suggest all of the claim limitations of the present invention. In fact, use of a spermicidal agent, an anti-STD agent, or mixtures thereof, with Banba's invention, will result in a totally opposite result, i.e. sperm-killing. Therefore, Applicants request that rejections under 35 U.S.C. 102(b) and 103(a) be removed.

Claims 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeLiso et al. (US Pat. 5,597,617) (herein after DeLiso).

The Office Action states, "DeLiso et al. expressly discloses an activated carbon composition falling within the scope of applicant's claims (Example 1-6, 11-13, 15, 16, claims 1, 2, 11)."

Applicants have amended their claims 11-13 to overcome the rejections in view of DeLiso. Specifically, Applicants have added a limitation to these claims that the composition also comprises of a safe and effective amount of a spermicidal agent, an anti-sexually transmitted disease agent, or mixtures thereof. Therefore, Applicants believe the claims as amended are not anticipated under 35 U.S.C. 102(b) in view of DeLiso.

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Claims 11-13 have also been rejected under 35 USC 103(a) as being unpatentable over DeLiso. Applicants respectfully traverse this rejection. Applicants believe the Office has not established a *prima facie* case of obviousness as required. DeLiso does not suggest or teach the use of activated carbon for preventing pregnancy or STDs. Further, there is no expectation of success as DeLiso teaches a method of making activated carbon for adsorbing and purifying fluid emissions from internal combustion engines at very high temperatures. And lastly, DeLiso does not meet or suggest all the claim limitations of the present invention. Applicants believe the amended claims are not obvious in view of DeLiso. Applicants request removal of 35 U.S.C. 103(a) rejection.

#### Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 112, first and second paragraph, 102(b), and 103(a). Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-13, and 15-18.

Respectfully submitted,  
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